

**AMENDMENT UNDER 37 C.F.R. § 1.111
U.S. Application No. 10/523,618 (Q117058)**

REMARKS

Claims 1-15 and 17-28 are in the application. Solely to advance prosecution and without prejudice or disclaimer, Applicants herewith amend claims 1, 2 and 26. Support for the amendments to claims 1, 2 and 26 is found, *inter alia*, at page 5. No new matter is added. Entry and consideration of the Amendment is respectfully requested.

I. Claims 1-15 and 17-28 Are Patentable Under 35 U.S.C. § 103

In paragraph 5, on page 3 of the Office Action, the Office rejects claims 1-15 and 18-28 under 35 U.S.C. § 103(a) as allegedly “anticipated” by Hoerstrup, further in view of Arru because Hoerstrup discloses a biodegradable support colonized by fibroblasts and/or myofibroblasts cells to form a matrix that is colonized with endothelial cells and a frame construction or “carrier”. Pages 3-4, Office Action. The Office admits that Hoerstrup fails to teach a degradable frame construction. Page 4, Office Action. The Office asserts that Arru remedies the deficiency of Hoerstrup because the reference discloses a metal stent structure material.

To maintain a rejection under 35 U.S.C. §103, the cited references must teach or suggest each and every element of the claim and the Office must identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does. *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398 (2007). Rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some *articulated reasoning* with some *rational underpinning* to support the legal conclusion of obviousness. As reiterated by the Supreme Court, an analysis for determining obviousness must include analysis of the underlying factual inquiries including, (1) determining

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the scope and content of the prior art; (2) ascertaining the differences between the claimed invention and the prior art; and (3) resolving the level of ordinary skill in the pertinent art. Use of hindsight is improper in determining whether a combination is obvious therefore, obviousness is found only where the prior art contains a teaching, suggestion or motivation to combine the individual elements. *Id.* It is well-settled law that a *prima facie* case of obviousness may be rebutted by showing that the art teaches away from the claimed invention. See *In re Geisler*, 116 F.3d 1465, 1471, 43 USPQ2d 1362, 1366 (Fed. Cir. 1997). Further, relevant law holds that a reference teaches away when a person of ordinary skill in the art, upon reading it, would be discouraged from following the path set out in the reference, or would be led in a path divergent from the path taken by the inventor. See *Monarch Knitting Mach. Corp v. Sulzer Morat Gmbh*, 139 F.3d, 877, 45 USPQ2d 1977 (Fed. Cir. 1998); *Para-Ordnance Mfg. v. SGS Importers Int'l Inc.*, 73 F.3d 1085, 37 USPQ2d 1237 (Fed. Cir. 1995); and *In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994).

Applicants respectfully disagree with the Office. The Office's conclusions are based on an incorrect characterization of the cited references, incorrect application of the references and improper law.

As an initial matter, the machine translation relied on by the Office is of poor quality. Applicants herewith submit a partial English translation of Hoerstrup (i.e., to Col. 5:50), including added column breaks. Consideration of the improved translation is respectfully requested.

The Office bases the legal conclusion of obviousness on the flawed technical assumption that because a frame and support can be made of PHA, frames and supports made of PHA have identical properties and therefore, according to the Office, the frame ("carrier") and support (also

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referred to as a “carrier”) are identical. The Office concludes that because the frame and support can be made of PHA and have identical properties “...the use of the terms ‘biodegradable’ and ‘poorly degradable’ becomes non-limiting”. Page 4, Office Action. Based on flawed assumptions, and disregard for recited essential features of the claimed invention, the Office concludes the invention recited by the claims is anticipated and obvious.

The property of PHA is dependent on, *inter alia*, chain length, production conditions and density. Frames and supports are not identical in the context of Applicant’s specification. In making the rejection the Office ignored the claim language and context.

As taught by Applicant, a support acts as a scaffold and topology template for cell growth and provides a three dimensional connective tissue matrix, which is beneficial and critical for a narrow window of time (e.g., until a connective tissue matrix is grown and formed). A degradable frame construction is recited by Applicant’s method, but the frame construction does not degrade prior to a year post-colonization. This feature permits post-implantation embedding of the structure in the host. Absent this feature, adaptation of the structure is impossible. The elements recited in the claims therefore, have different properties.

Hoerstrup fails to teach or suggest the frame construction recited in Applicant’s claims. Hoerstrup fails to teach or suggest Applicant’s *biodegradable* frame construction. Hoerstrup fails to teach or suggest attachment of a support to a frame construction. Hoerstrup also fails to teach or suggest a frame construction which does not degrade prior to a year post-colonization. Thus, it is impossible for the Office to assert a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does because essential features of the claimed invention are not taught or suggested by the reference.

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The deficiencies of Hoerstrup are not remedied by Arru. In fact, Arru leads a person having ordinary skill in the art away from the claimed invention. Arru contains information relating to the production of heart valve implants using tissue sheets from animals. Arru, col. 1, lines 23-25. Arru guides the ordinarily skilled artisan to a divergent process and product, not the claimed invention. Arru, col. 3, line 1-23. Arru fails to disclose use of a pulsatile flow chamber. Arru directs the artisan to the use of metalaic, non-biodegradable materials. Arru, col. 5, lines 35-46. The disadvantages of Arru's approach includes lack of growth and adaptation to a host (i.e., patient). Further, a person of ordinary skill in the art having common sense at the relevant time would not have reasonably looked to Hoerstrup to solve a problem already solved by Arru. The Examiner has not provided a sufficient reason or explicit analysis of why the disclosures of Hoerstrup and Arru should be combined because the ordinarily skilled person would not make the alleged combination. Assuming arguendo a person having ordinary skill in the art would combine Hoerstrup and Arru, *which he would not*, it is impossible to arrive at Applicant's invention because material features of the claimed invention are absent from the cited references. The combination proposed by the Office can only be based on improper hindsight.

The Federal Circuit recently held that in a unpredictable field, such as tissue engineering, the selection of a specific combination (here, a biodegradable support that begins degrading at least 8 days post colonization and is completely degraded no later than 3 months after colonization and a slowly degradable frame which does not degrade prior to a year after colonization) is not obvious when the prior art contained no specific prediction of how that *exact* combination would work. *Abbott Labs. v. Sandoz, Inc.*, 2008 U.S. App. LEXIS 21880, October 21, 2008. The assertion by the Office that the production of heart valve implants using tissue sheets from animals as disclosed in Arru, in combination with the biodegradable support

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(colonized by fibroblasts and/or myofibroblasts cells to form a matrix that is colonized with endothelial cells) and a frame construction or “carrier” of Hoerstrup renders obvious Applicant’s invention is improper. There is no specific prediction in Arru or Hoerstrup of how Applicant’s *exact* invention would work.

Regarding claim 2, Arru discloses information relating to fixing tissue constructs, based on animal tissue sheets, to a frame construction *after* subjecting it to a pressure difference. Arru teaches away from Applicant’s invention in this respect. A person of ordinary skill in the art would be led down a path divergent from the path taken by the inventor because Arru discloses a support attached to a frame construct on which a connective tissue matrix is grown. Applicant’s method is simpler and more advantageous (e.g., results in enhanced attachment of the connective tissue structure to the frame, etc.).

Accordingly, for the foregoing reasons and the reasons of record, claims 1-15 and 18-28 are patentable under 35 U.S.C. § 103 because the Office failed to properly determine the scope and content of the prior art; refused to accord weight to the language of the claims; relied on impermissible hindsight, failed to identify a teaching, suggestion or motivation to combine the individual elements; and failed to acknowledge that the art teaches away from the claimed invention. The rejection cannot be maintained.

Withdrawal of the obviousness rejection is respectfully requested.

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

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The U.S. Patent and Trademark Office is hereby directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



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23373

CUSTOMER NUMBER

Date: April 2, 2010